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EXPERIENCE FROM THE FIELD

Gastroenterology

Editing combined multichannel intraluminal impedance and pH monitoring tracings

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Multichannel intraluminal impedance (MII-pH) monitoring has become the gold standard for assessment of gastroesophageal reflux (GER) in infants, children, and adults.[1] The primary advantage of MII-pH monitoring over pH monitoring alone is the ability to detect and quantify nonacid GER (pH ≥ 4). Multiple impedance channels along the length of catheter permit the monitoring of proximal movement of refluxed bolus within the esophageal lumen and the assessment of clearance efficiency. In addition to being able to measure the frequency and duration of refluxed boluses, one of the most important applications of the technology is the ability to assess the temporal relationships between all GER types with reported symptoms.[2]

There are some challenges to the use of MII-pH monitoring. First, the MII-pH system is costly[2,3] and therefore not available in every center. Second, operationalizing the execution, the analysis, and the interpretation of the studies all require considerable expertise.[3,4] Third, considerable time commitment is required to generate an accurate and comprehensive analysis.[5,6]

Several post-study modifications should be considered before the data can be analyzed and interpreted. While most users are aware that MII-pH tracings require editing, they may not be aware of all the editing that may be necessary for a given tracing.

The analysis of the MII-pH studies should be given sufficient time and attention to detail so that it can be relied upon for the development of appropriate clinical management strategies.[7] The fact that MII-pH monitoring is moderately invasive, collects data for 24 h, and can lead to significant changes in clinical decision-making, should incentivize thorough editing to maximize the accuracy of the data extracted from each tracing.

1 | EDIT TYPES

Editing types are divided into three groups (deletions, insertions, and miscellaneous) and are listed in Table 1.

1.1 | Deletion edits

1. Many MII algorithms employ an autoscan that produces numerous false positives. These events need to be deleted by selecting the event and pushing the delete button. Supporting Information S1: Figure 1 illustrates an example wherein the algorithm has constructed a GER between two swallows.

TABLE 1 Types of edits for impedance-pH tracings.

Deletion edits
1. False positives
2. Esophageal acidifications following a swallow
3. Esophageal acidifications immediately before and after a meal
4. Slow pH-Drifts and pseudo-reflux
5. Periods of the study when impedance-pH channels flatline (signal loss)
6. GER that occurs during a meal but within a symptom window
7. Multiple symptom records
8. Early portion of study following catheter repositioning
Insertion edits
1. False negatives
2. Additional symptom types not programmed into recorder box
3. Written diary entries (clinically relevant) not added to electronic diary
Miscellaneous edits
1. Fine-tuning the duration in the distal impedance channel (Z6) and the proximal extent of autoscan-tagged events
2. Separating GER events that were combined during autoscan

Abbreviation: GER, gastroesophageal reflux.

2. Occasionally, a patient will eat or drink acidic foods or beverages without documenting it. Esophageal acidifications that are preceded by a swallow, should be edited from the tracing[3,8] by either tagging it as an artifact using artifact markers or, when possible [depending upon the platform], enabling the pH-reflux markers, and deleting those pH events that follow the swallow.
3. If the meal start button is pushed after a noncompliant (or unsupervised) patient begins to eat an acidic meal and if the esophagus remains acidified after the meal stop button has been pushed, the resultant non-GER-related esophageal acidifications need to be ignored with the insertion of artifact markers. The flanks of mealtimes should always be inspected during editing.[9]
4. Occasionally, in a quiescent esophagus, the pH slowly "drifts" in and out of acidity (<pH 4) without being associated with corresponding drops in impedance. While slow pH drifts without impedance should be included for calculations of acid GER (AGER) index (percentage of time the esophagus is acidified by GER), they should not be considered individual GER episodes.[8] Pseudo-reflux,[10] indicated by the gradual decline of the pH waveform to <pH 4 followed by a quick return to baseline, should also be deleted.[2]
5. Occasionally, the catheter is accidentally pulled out, mostly during unsupervised sleep. The autoscan of most platforms will automatically create an artifact for the flatlined portions of the tracing. If it does not, these and other loss-of-signal regions, need to be ignored with the insertion of artifact markers to flank the ignored region(s).
6. A GER event that occurs during a meal and also within an overlapping 2-min symptom window, will be temporally associated with that symptom even though analysis settings are set to exclude meals.[11] These GER events should be deleted so that they do not influence symptom-reflux correlations.
7. Occasionally, a symptom button is pushed multiple times, within a short period, and ultimately produces an error (e.g., symptom association probability [SAP] = not a number ["NAN"]). We have found that, deleting all but one of the repeated symptom events within a 2-min window results in restoration of a numeric symptom assessment value. Others have suggested a 4-min window.[7] An agreed-upon standard window for deleting duplicate/excessive symptoms has yet to be established. Further studies are needed to drive research-based decision-making regarding the deletion of repeated entries.
8. Occasionally, radiological confirmation of catheter placement shows that the catheter needs to be repositioned. Artifact markers are used to span the duration from when the study began to the time point at which the catheter is successfully repositioned.[3]

1.2 | Insertion edits

1. When the baseline impedance (BI) is low, there will be false negatives (i.e., impedance-detectable reflux events that are not tagged by the autoscan). Tracings with low BI require meticulous visual screening to identify and properly tag GER events. In Supporting Information S1: Figure 2, we see an example of how GER events can be identified and properly tagged when the auto-scale impedance is adjusted, and a contour plot is used.
2. Occasionally, the referring physician will request that a 4th symptom be monitored. Once the study is completed, the MII-pH analyst will manually enter the additional symptom occurrences into the electronic diary. Constant attendants and/or caregivers should be instructed to not document symptoms that only occurred on the day of the test as these symptoms are likely due to the presence of the catheter.
3. A written diary of events should be maintained during the study.[3] When the study is complete, the diary should be examined and recorded events should be cross-referenced with those that were logged directly into the recording box.

1.3 | Miscellaneous edits

1. A major part of the editing process is the "fine-tuning" of tagged (by autoscan) impedance events. There are two characteristics of an impedance-detected GER event that are important; the duration of the GER in the distal esophagus (Z6) and the proximal extent of the reflux event (does the reflux frequently approach the oropharynx and thus place the patient at increased risk of aspiration) Supporting Information S1: Figure 3 depicts a nonacid

GER event in which the autoscan neglected to include the proximal-most waveform (Z1). The duration in any of the other channels is unimportant because they rarely are considered in the assessment report. The reflux duration in either channel is defined by the points of bolus entry (impedance waveform drops to <50% of baseline) and bolus exit (impedance waveform ascends to ≥50% of baseline).[8]

2. Occasionally, an impedance-detected reflux event will be tagged (by autoscan) as an obviously "combined" or "conjoined" event. This occurs when the impedance waveform in the distal channel never ascends to 50% of baseline before the second event occurs.[12] To arrive at a more accurate inventory of reflux events (i.e., the number of transient relaxations of the lower esophageal sphincter), the analyst might consider separating the events as previously described.[12]

2 | DISCUSSION

When we train scientists and clinicians to work with MII-pH tracings, we generally focus on the identification and tagging of impedance-detected GER events. However, the reliability of the data extracted from a MII-pH tracing is dependent on comprehensive and thorough editing of the entire tracing. While the proper training and experience of the analyst is important, the quality of the instruction provided to the patient, constant attendant and/or parent/guardian is also critical.[3]

This paper outlines several types of editing that is recommended to ensure the accuracy of the extracted data. The most novel edit type is the importance of examining the borders of individual meals for meal-related acidification. Despite pre-test instructions to avoid acidic foods and beverages, the reality is that most patients are not aware of the pH of all foods/drinks; consequently, if they were to start to eat or drink before hitting the meal button or if they do not wait until the esophagus has neutralized to push the button again, one or both meal borders will be acidic.[9] Left unedited, these meal-related acidifications could increase the AGER index to above threshold levels.

We expect that future improvements in the MII-pH software's algorithm will reduce the time commitment for the analyst. Until then, thorough editing of MII-pH tracings is encouraged to correct for inherent low specificity, improve the accuracy of the data analysis and ultimately lead to good clinical outcomes. Also, with these MII-pH edits in mind, there can be a reduction in the relatively high intra- and interobserver variability.[2]

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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